

REMARKS

Claims 1-5, 7, 9-15 and 25-28 have been canceled, and claims 6, 8, 14 and 16-23 have been amended. Upon entry of the amendment, claims 6, 8 and 16-24 are pending. Support for the amendments can be found, for example, in the claims as originally filed.

Objections

Claim 9 is objected to for dependency on withdrawn claim 1. Claim 9 has been canceled rendering the objection moot.

Rejections

Rejections under 35 U.S.C. § 101

Claims 3-12 and 14-25 stand rejected under 35 U.S.C. § 101 because the claimed invention is allegedly not supported by either a specific or substantial asserted utility or a well established utility. The Examiner argues that the specification does not disclose a specific disease in humans linked to a disruption in Kir5.1.

The claims as amended are drawn to a transgenic mouse comprising a homozygous disruption in a Kir5.1 gene, where the mouse exhibits anxiety, dwarfism, decreased body size, decreased body weight or decreased spleen weight. Each of these phenotypes was observed in the Kir5.1 knockout mouse relative to the wild-type mouse. Each therefore represents a disorder that is associated with the function of the Kir5.1 gene. One skilled in the art would immediately recognize the utility of the knockout mouse for further study of these disorders and their association with the Kir5.1 gene. (MPEP § 2107). Assignee Deltagen is in the business of generating knockout mice and providing them to commercial and academic institutions for the purpose of studying gene function. The Kir5.1 knockout mouse has been ordered by at least four (4) entities including Merck, Pfizer and GlaxoSmithKline, three of the world's largest pharmaceutical companies. This interest in studying these knockout mice is more than adequate evidence that one skilled in the art immediately recognizes the utility of the Kir5.1 knockout mouse. ("A patent system must be related to the world of commerce rather than to the realm of philosophy." *Brenner v Manson*, 383 U.S. 519, 148 U.S.P.Q. 689, 696 (1966)).

Applicant respectfully points out that he is not claiming a method of treating humans and therefore should not be required to establish a correlation between the disorders and human

Kir5.1 gene mutations. Applicant submits that the utility requirement of the invention as claimed is met and respectfully requests withdrawal of the rejection.

Rejections under 35 U.S.C. § 112, paragraph 1

Claims 3-12 and 14-25 have been rejected since the claimed invention allegedly lacks utility, one skilled in the art would not know how to use the invention.

Applicant disagrees. As discussed above, the claimed invention satisfies the utility requirement of section 101. Therefore, one skilled in the art would know how to use the invention.

Examiner further argues that the specification does not reasonably provide enablement for any animal. The claims have been amended to recite “transgenic mouse.”

The Examiner also argues that the specification does not enable making or using a transgenic with a wild-type phenotype, as the claims do not recite any specific phenotypes. The claims have been amended to recite specific phenotypes.

It is also argued that the specification does not teach how to make any cell with a Kir5.1 gene disruption. The claims have been amended to recite that the cells are derived from the knockout mice.

Claim 9 has been rejected on grounds it does not recite mouse ES cells. The claim has been canceled.

Claims 10-12 have been rejected as the specification allegedly does not provide adequate guidance for using the mouse to determine compounds for modulation of Kir5.1. The claims have been canceled.

Rejections under 35 U.S.C. § 112, paragraph 2

Claims 10-12, 14, 15, 17, 18, 21, 24 and 25 have been rejected on grounds of indefiniteness.

Claims 10-11 have been rejected as the mice do not express Kir5.1. The claims have been canceled.

Claim 14 stands rejected as the term “significant expression” is indefinite. The claim has been canceled.

Claims 17 and 18 have been rejected as the claim limitations do not further limit the invention claimed in independent claim 16. The claims have been amended to address the Examiner’s concerns.

Claim 21 has been rejected on the ground that it does not further limit the claims upon which it is dependent. The claim has been appropriately amended.

Claim 25 stands rejected on ground of indefiniteness. The claim has been canceled.

Rejections under 35 U.S.C. § 103

Claims 3-9, 14 and 24 have been rejected as obvious over Signorini in view of Mouri. Signorini is cited as teaching a transgenic mouse having a disruption in the Kir3.2 gene. Mouri is cited as teaching the nucleic acid sequence of the murine Kir5.1 gene. The Examiner argues that one skilled in the art would have been motivated to disrupt the Kir5.1 gene to determine the function of Kir5.1 in the brain in vivo.

Applicant respectfully disagrees. A general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out. (In re Deuel, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995)). A desire to determine gene function is insufficient to render the present invention obvious as the references do not teach or disclose a Kir5.1 knockout mouse and in particular one with the claimed phenotypes. Applicant submits that the claimed invention is nonobvious, and respectfully requests withdrawal of the rejection.

Additional Remarks with respect to Utility

Applicant respectfully submits that the Examiner's arguments with respect to obviousness are directly contradictory to and inconsistent with his arguments regarding utility. The Examiner argues that one skilled in the art would have been motivated to disrupt the Kir5.1 gene in the mouse to determine its function yet at the same time argues that one skilled in the art would not understand why such a mouse once created would be useful. The motivation cited by the Examiner to create the knockout mouse should sufficiently support a well-established utility for the Applicant's claimed invention. Reconsideration is respectfully requested.

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1271 under Order No. R-902.

Respectfully submitted,

Date: August 19, 2004

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